

Protocol Date June 21, 2018

Study Protocol Title:

Molekule for allergic rhinitis/asthma

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Background:

In the United States, the incidence of respiratory allergies and asthma are increasing, with 10-40% of the population suffering from allergies¹ and 8% suffering from asthma². The direct and indirect health costs and decrement in quality of life from these illnesses are substantial^{2,3}. While these symptoms are typically attributed to aeroallergens, there are particulate matter and volatile organic compounds (VOCs) that act as irritants that can also evoke symptoms. Local air filtration has shown some ability to decrease allergen counts in the air and thus improve the symptoms experienced by allergy and asthma sufferers under certain conditions⁴. However, to date the efficacy of a comprehensive air purification system, particularly with high efficiency particulate air (HEPA) filtration, as a sole intervention modality has been equivocal and the extent of air filtration remains suboptimal.

Photo-electrochemical oxidation (PECO) is a revolutionary new technology for providing an air purification solution. In addition to physical filtration, a photo-electrochemical reaction takes place on the surface of a nano-coated filter leading to the oxidation of organic matter. These processes allow for the destruction of organic material 1000 times smaller than what a HEPA filter can capture^{5,6}. Thus, PECO not only removes but can also efficiently destroy organic matter, bacteria, viruses, mold, and VOCs converting them into their trace elements⁷.

Specific Goals/Objectives:

Primary Objective: To assess the efficacy of the portable Molekule air purifier in reducing symptoms from allergic rhinitis and asthma.

Hypothesis: The portable Molekule air purifier will significantly improve allergy and asthma symptom scores in patients with allergic rhinitis and asthma.

Study Design:

- Randomized double blinded placebo, controlled trial for participants using the Molekule air purifier or placebo unit for a total of 4 weeks. The portable unit will be placed at the participants bedside and will be running continuously. Screening survey for eligibility will take place and unit will be shipped and ready for use within 1 week. Device use will take place for 4 weeks and then there will be an exit survey. Primary endpoint is change in CARAT scores. Unit should be running >18 hours per day including at night time in the participant bedroom

Patient Selection:

Inclusion Criteria:

- Chronic allergic rhinitis and/or conjunctivitis by history
- History of adult asthma requiring medications now or in the past
- Age ≥18
- CARAT score less than 24

Exclusion Criteria:

- Use of systemic corticosteroids within 14 days of study initiation
- Treatment with biologic agents or allergen immunotherapy
- Treatment with other immunomodulators (cyclosporine, azathioprine, hydroxychloroquine, etc)

Study Endpoints

Primary Endpoints:

- CARAT scores (see survey below)

Secondary Endpoints/exploratory:

- Upper airway scores per CARAT
- Lower airway scores per CARAT
- Change in allergy medication use
- Change in asthma medication use
- Asthma exacerbations requiring clinic or ER visits
- Compliance of air purifier use

Statistical Analysis:

A sample size of 110 subjects, 55 in each arm, is sufficient to detect a clinically important difference of 3.5 between groups assuming a standard deviation of 6.43 using a two-tailed t-test of difference between means with 80% power and a 5% level of significance.

SigmaStat 4.0

Reference: Sakpal TV. Sample Size Estimation in Clinical Trial. Perspectives in Clinical Research. 2010;1(2):67-69.

Software: SigmaStat V4.0

Additional items:

- 1)Obtain IRB approval-2-4 weeks
- 2)Manufacture placebo and active units-8 weeks (I am estimating that we will be able to have approximately 60 units (30 + 30) made for this purpose)
- 3)Screen participants from Molekule mailing list, begin enrollment and ship units
- 4)Those randomized to placebo will be contacted at the conclusion of the study and will be able to test the units (data not planned to be collected)

References:

1. Settipane RA. Demographics and epidemiology of allergic and nonallergic rhinitis. *Allergy Asthma Proc.* 2001;22(4):185-189.
2. Loftus PA, Wise SK. Epidemiology and economic burden of asthma. *Int Forum Allergy Rhinol.* 2015;5 Suppl 1:S7-10.
3. Schoenwetter WF, Dupclay L, Jr., Appajosyula S, Botteman MF, Pashos CL. Economic impact and quality-of-life burden of allergic rhinitis. *Curr Med Res Opin.* 2004;20(3):305-317.
4. Sublett JL. Effectiveness of air filters and air cleaners in allergic respiratory diseases: a review of the recent literature. *Curr Allergy Asthma Rep.* 2011;11(5):395-402.
5. Goswami DY. Decontamination of ventilation systems using photocatalytic air cleaning technology. *TRANSACTIONS-AMERICAN SOCIETY OF MECHANICAL ENGINEERS JOURNAL OF SOLAR ENERGY ENGINEERING.* 2003;125(3):359-365.
6. Zhang Y, Stefanakos EK, Goswami DY. Effect of photocatalytic surface roughness on reactors effectiveness for indoor air cleaning. *Building and Environment.* 2013;61:188-196.

7. Dalrymple OK, Stefanakos E, Trotz MA, Goswami DY. A review of the mechanisms and modeling of photocatalytic disinfection. *Applied Catalysis B: Environmental*. 2010;98(1):27-38.



Control of Allergic Rhinitis and Asthma Test

3-05-2018

During the last 4 weeks, because of your asthma/rhinitis/allergy how many times, on average, did you experience:

	Never	Up to 2 days per week	More than 2 days per week	Almost every day or every day
1. Blocked nose ? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Sneezing? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Itchy nose? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Runny nose? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Shortness of breath/dyspnoea? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Wheezing in the chest? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Chest tightness upon physical exercise? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Tiredness/limitations in doing daily tasks? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Woke up during the night because of your asthma/rhinitis/allergy? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

During the last 4 weeks, because of your asthma/rhinitis/allergy, how many times did you have to:

	I am not taking any medicines	Never	Less than 7 days	7 or more days
10. Increase the use of your medications? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* All questions are mandatory

Total Score: 0

Scores higher than 24 indicate good disease control

Score of the upper airway (item 1-4): 0

Controlled if score is >8

Score of the lower airway (item 5-10): 0

Controlled if score is ≥16